This l sting of claims will replace all prior versions, and listings, of claims in the application:

LIST] NG OF CLAIMS:

1. — 172. (Canceled)

173. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate.

174. **(Previously presented)** A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm^2/g.

175. **(Currently Amended)** A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital

atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone ~~is micronized drospirenone~~ has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm.

176. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is: estradiol, an estradiol sulfamate, estradiol valerate, estradiol benzoate, ethinyl estradiol, estrone, estriol, estriol succinate, a conjugated estrogen or a mixture thereof.

177. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is: estradiol, an estradiol sulfamate, estradiol valerate, estradiol benzoate, estrone, estrone sulfate or a mixture thereof.

178. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is estradiol.

179. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is in micronized form.

180. (Previously presented) A method according to claim 178, wherein the estradiol is in micronized form.

181. (Previously presented) A method according to claim 173, 174, or 175, wherein the dose of drospirenone corresponds to 15 to 70 mg per cycle.

182. (Previously presented) A method according to claim 173, 174, or 175, wherein the amount of drospirenone corresponds to a daily dose ranging from 0.25 to 10 mg.

183. (Previously presented) A method according to claim 178, wherein the amount of estradiol corresponds to a daily dose ranging from 0.1 to 5 mg.

184. (Previously presented) A method according to claim 178, wherein the amount of estradiol corresponds to a daily dose of about 0.1 to 5 mg.

185. (Previously presented) A method according to claim 178, comprising administering estradiol in a daily dose of 1 to 3 mg and drospirenone in a daily dose of 1 to 3.5 mg

186. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen and/or the drospirenone is administered in the form of a tablet, capsule or pill.

187. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is: estrone sulfate, 17β-estradiol sulfate, 17α-estradiol sulfate, equilin sulfate, 17β-dihydroequilin sulfate, 17α-dihydroequilin sulfate, equilenin sulfate, 17β-dihydroequilenin sulfate, 17α-dihydroequilenin sulfate or a mixture thereof.

188. (Previously presented) A method according to claim 173, 174, or 175, wherein the daily dose of estrogen is 1 to 3 mg, and the daily dose of drospirenone is 0.25 to 10.0 mg.

189. (Previously presented) A method according to claim 173, 174, or 175, wherein the drospirenone is in the form of a prodrug of the compound.

190. (Currently Amended) A method according to claim 173, 174, or 175, wherein the drospirenone is provided ~~in a daily dose of 0.25 to 8.0 mg,~~ in a form whereby it is exposed to the gastric environment upon dissolution.

191. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is sprayed from a solution onto particles of an inert carrier.

192. (Currently Amended) A method according to claim 173, 174, or 175, wherein the estrogen ~~is micronized~~ has a particle size distribution such that 100% of the particles have a diameter of ≤ 15.0 μm, 99% of the particles have a diameter of ≤ 12.5 μm, 95% of the particles have a diameter of ≤ 10.0 μm and 50% of the particles have a diameter of ≤ 3.0 μm.

193. - 194. (Canceled)

195. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen and/or drospirenone are provided together with a carrier which promotes rapid dissolution of the estrogen and/or drospirenone.

196. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen and/or drospirenone is provided together with a carrier which comprises carboxymethylcellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, gelled starch gelatin or polyvinylpyrrolidone.

197. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen and/or drospirenone is provided together with a carrier which comprises polyvinylpyrrolidone.

198. (Previously presented) A method according to claim 178, wherein the dose of estradiol is about 1 mg.

199. (Previously presented) A method according to claim 178, wherein the dose of estradiol is about 1 mg and the dose of drospirenone is about 0.5 mg, about 1 mg about 2 mg or about 3 mg.

200. (Previously presented) A method according to claim 173, 174, or 175, wherein the dose of drospirenone is from 0.25 to 6.0 mg.

201. (Previously presented) A method according to claim 173, 174, or 175, wherein the dose of drospirenone is from 0.5 to 4.5 mg.

202. (Previously presented) A method according to claim 173, 174, or 175, wherein the dose of drospirenone is from 1.5 to 3.5 mg.

203. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900

ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen including:

a first treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg;

following the first treatment period, a second treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the second treatment period, a third treatment period of 4 to 8 days comprising administering either: a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.25 to 5 mg or administering a daily dosage unit of a placebo or blank.

204. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm^2/g,

according to a treatment regimen including:

a first treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg;

following the first treatment period, a second treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the second treatment period, a third treatment period of 4 to 8 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.25 to 5 mg or administering a daily dosage unit of a placebo or blank.

205. (Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety,

poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone ~~is micronized drospirenone~~ has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm,

according to a treatment regimen including:

a first treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg;

following the first treatment period, a second treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the second treatment period, a third treatment period of 4 to 8 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.25 to 5 mg or administering a daily dosage unit of a placebo or blank.

206. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural

menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen including:

a first treatment period of at least 21 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the first treatment period, a second treatment period of no more than 7 days comprising administering: either a daily dosage unit of a placebo or blank or a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg.

207. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm^2/g,

according to a treatment regimen including:

a first treatment period of at least 21 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the first treatment period, a second treatment period of no more than 7 days comprising administering: either a daily dosage unit of a placebo or blank or a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg.

208. **(Currently Amended)** A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone ~~is micronized drospirenone~~ has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm,

according to a treatment regimen including:

a first treatment period of at least 21 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the first treatment period, a second treatment period of no more than 7 days comprising administering: either a daily dosage unit of a placebo or blank or a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg.

209. **(Previously presented)** A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen including:

administering for 21 to 28 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg.

210. **(Previously presented)** A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural

menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm^2/g,

according to a treatment regimen including:

administering for 21 to 28 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg.

211. (Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss

of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone ~~is micronized drospirenone~~ has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm,

according to a treatment regimen including:

administering for 21 to 28 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg.

212. (Previously presented) A method according to claim 209, 210 or 211, wherein the daily dosage units are administered for 1 to 12 cycles of 28 days per cycle.

213. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital

atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen.

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen wherein the estrogen is administered continuously.

214. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm^2/g.

according to a treatment regimen wherein the estrogen is administered continuously.

215. (Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone ~~is micronized drospirenone~~ has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm,

according to a treatment regimen wherein the estrogen is administered continuously.

216. (Previously presented) A method according to claim 213, 214 or 215 wherein the drospirenone is administered continuously.

217. (Previously presented) A method according to claim 213, 214 or 215, wherein the drospirenone is administered in sequential intervals.

218. (Previously presented) A method according to claim 217, wherein the estrogen dosage is lower for the first 1 to 7 days immediately after finishing a sequential interval of administration of drospirenone.

219. (Previously presented) A method according to claim 218, wherein the estrogen is administered continuously for 21 to 30 days and drospirenone is administered in a 3-day-on-3-day-off cycle.

220. (Previously presented) A method according to claim 219, wherein drospirenone is administered on days 4 through 6, 10 through 12, 16 through 18, 22 through 24, and 28 through 30.

221. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular

disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen wherein the estrogen and the drospirenone are each administered such that there is a treatment-free interval of 1-7 days within each cycle.

222. **(Previously presented)** A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm^2/g

according to a treatment regimen wherein the estrogen and the drospirenone are each administered such that there is a treatment-free interval of 1-7 days within each cycle.

223. (Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone ~~is micronized drospirenone~~ has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm,

according to a treatment regimen wherein the estrogen and the drospirenone are each administered such that there is a treatment-free interval of 1-7 days within each cycle.

224. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen including:

a first treatment period of administering for 20 to 24 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg, and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg for the last 10 to 12 days of said 20 to 24 days, and

following the first treatment period, either:

administering for 4 to 8 days a daily dosage unit comprising no active ingredient,

administering for 4 to 8 days a daily dosage of unit comprising estradiol in an amount less than daily dosage unit taken for said 20 to 24 day administration of estradiol, or

not administering any dosage units for 4 to 8 days.

225. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm^2/g

according to a treatment regimen including:

a first treatment period of administering for 20 to 24 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg, and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg for the last 10 to 12 days of said 20 to 24 days, and

following the first treatment period, either:

administering for 4 to 8 days a daily dosage unit comprising no active ingredient,

administering for 4 to 8 days a daily dosage of unit comprising estradiol in an amount less than daily dosage unit taken for said 20 to 24 day administration of estradiol, or

not administering any dosage units for 4 to 8 days.

226. (Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone ~~is micronized drospirenone~~ has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm,

according to a treatment regimen including:

a first treatment period of administering for 20 to 24 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg, and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg for the last 10 to 12 days of said 20 to 24 days, and

following the first treatment period, either:

administering for 4 to 8 days a daily dosage unit comprising no active ingredient,

administering for 4 to 8 days a daily dosage of unit comprising estradiol in an amount less than daily dosage unit taken for said 20 to 24 day administration of estradiol or

not administering any dosage units for 4 to 8 days.

227. (Previously presented) A method for hormone replacement therapy comprising orally administering to a woman;

an estrogen in an amount sufficient for hormone replacement therapy, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900

ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate.

228. (Previously presented) A method for hormone replacement therapy comprising orally administering to a woman;

an estrogen in an amount sufficient for hormone replacement therapy, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm^2/g

229. (Currently Amended) A method for hormone replacement therapy comprising orally administering to a woman;

an estrogen in an amount sufficient for hormone replacement therapy, and

drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone ~~is micronized drospirenone~~ has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm.

230. (Previously presented) A method according to claim 173 or 174, wherein the drospirenone is sprayed from a solution onto particles of an inert carrier.

231. (Canceled)

232. (Canceled)

233. (New) A method according to claim 175, 205, 208, 211, 215, 223, 226 or 229, wherein the drospirenone has a particle size distribution such that, additionally, ≤ 20% of the particles have a diameter of ≥ 10 μm and ≤ 30 μm.

234. (New) A method according to one of claims 203 to 211, 213 to 215 or 221 to 229, wherein the drospirenone is provided in a form whereby it is exposed to the gastric environment upon dissolution.

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